SECTION 1. IDENTIFICATION

Product name : Zeranol Formulation

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Carcinogenicity : Category 2
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Endocrine system, Liver)

GHS label elements
Hazard pictograms : 
Signal Word : Danger
Hazard Statements : May form combustible dust concentrations in air.
H351 Suspected of causing cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs (Endocrine system, Liver) through prolonged or repeated exposure.

Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection
and face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical attention.

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

#### Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zeranol</td>
<td>26538-44-3</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Boric acid</td>
<td>10043-35-3</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

**General advice**
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

**If inhaled**
If inhaled, remove to fresh air.
Get medical attention.

**In case of skin contact**
In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

**In case of eye contact**
If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

**If swallowed**
If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed**
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
Suspected of causing cancer.
May damage fertility. May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.
SAFETY DATA SHEET

Zeranol Formulation

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- High volume water jet

Specific hazards during fire fighting:
- Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
- Do not use a solid water stream as it may scatter and spread fire.
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Boron oxides
- Metal oxides

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for fire-fighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spills cannot be contained.

Methods and materials for containment and cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to
determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Inert or nuisance dust</th>
<th>50 Million particles per cubic foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value type (Form of exposure): TWA (total dust)</td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td>15 mg/m³</td>
<td>Value type (Form of exposure): TWA (total dust)</td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
<tr>
<td>5 mg/m³</td>
<td>Value type (Form of exposure): TWA (respirable fraction)</td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
</tbody>
</table>
15 Million particles per cubic foot
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3

Dust, nuisance dust and particulates
10 mg/m³
Value type (Form of exposure): PEL (Total dust)
Basis: CAL PEL

5 mg/m³
Value type (Form of exposure): PEL (respirable dust fraction)
Basis: CAL PEL

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>zeranol</td>
<td>26538-44-3</td>
<td>TWA</td>
<td>2 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td>Boric acid</td>
<td>10043-35-3</td>
<td>TWA (Inhalable particulate matter)</td>
<td>2 mg/m³ (Borate)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Inhalable particulate matter)</td>
<td>6 mg/m³ (Borate)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate  matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**Engineering measures**: Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

**Personal protective equipment**

**Respiratory protection**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other
circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material: Chemical-resistant gloves
Remarks: Consider double gloving.

Eye protection

Material: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection

Material: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures

Material: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: yellow
Odor: odorless
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: No data available
Flammability (solid, gas): May form combustible dust concentrations in air.
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: No data available
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility: insoluble
Partition coefficient: n-octanol/water: No data available
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Dust deflagration index (Kst): 180 m.b_/s
Minimum ignition energy: 5 - 10 mJ
Particle size: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
May form combustible dust concentrations in air.
Can react with strong oxidizing agents.
Conditions to avoid: Heat, flames and sparks.
Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.
SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:

Acute oral toxicity : 
Method: Calculation method

Components:

zeranol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available

Boric acid:

Acute oral toxicity : LD50 (Rat): 3,450 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 2.03 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: OECD Test Guideline 403
  Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 423
  Assessment: The substance or mixture has no acute oral toxicity
  Remarks: Based on data from similar materials
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
  Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.
Components:

zeranol:
| Remarks | No data available |

Boric acid:
| Species | Rabbit |
| Result | No skin irritation |

Magnesium stearate:
| Species | Rabbit |
| Result | No skin irritation |
| Remarks | Based on data from similar materials |

Serious eye damage/eye irritation

Not classified based on available information.

Components:

zeranol:
| Remarks | No data available |

Boric acid:
| Species | Rabbit |
| Result | No eye irritation |

Magnesium stearate:
| Species | Rabbit |
| Result | No eye irritation |
| Remarks | Based on data from similar materials |

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

zeranol:
| Remarks | No data available |

Boric acid:
| Test Type | Buehler Test |
| Routes of exposure | Skin contact |
| Species | Guinea pig |
| Method | OECD Test Guideline 406 |
| Result | negative |
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Zeranol Formulation

Magnesium stearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**zeranol:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: negative

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Cytogenetic assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Boric acid:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Test Type: In vitro mammalian cell gene mutation test
Result: equivocal

Test Type: Chromosome aberration test in vitro
Result: negative

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity
Suspected of causing cancer.

Components:
zeranol:
- Species: Mouse
- Application Route: Oral
- Exposure time: 2 Years
- Result: positive
- Target Organs: female reproductive organs, Pituitary gland

- Species: Rat
  - Application Route: Oral
  - Exposure time: 2 Years
  - Result: negative

- Species: Dog
  - Application Route: Oral
  - Exposure time: 2 Years
  - Result: negative

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

Boric acid:
- Species: Mouse
- Application Route: Ingestion
- Exposure time: 103 weeks
- Result: negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:
zeranol:
- Effects on fertility
  - Test Type: Three-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Oral
  - Result: No significant adverse effects were reported
Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
General Toxicity F1: LOAEL: 3 mg/kg body weight  
Symptoms: Reduced body weight  
Result: Effects on reproduction parameters.

Test Type: Fertility  
Species: Rat, males  
Application Route: Oral  
Fertility: LOAEL: 1.25 mg/kg body weight  
Symptoms: Reduced fertility

Effects on fetal development: Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 2 mg/kg body weight  
Symptoms: Reduced number of viable fetuses.  
Result: Embryolethal effects., No teratogenic effects.

Boric acid:  
Effects on fertility: Test Type: Three-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: positive

Effects on fetal development: Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Ingestion  
Result: positive

Reproductive toxicity - Assessment: Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

Magnesium stearate:  
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative
### Remarks:
Based on data from similar materials

### Effects on fetal development
**Test Type:** Embryofetal development  
**Species:** Rat  
**Application Route:** Ingestion  
**Result:** negative  
**Remarks:** Based on data from similar materials

### STOT-single exposure
Not classified based on available information.

### STOT-repeated exposure
Causes damage to organs (Endocrine system, Liver) through prolonged or repeated exposure.

#### Components:

<table>
<thead>
<tr>
<th><strong>Component</strong></th>
<th><strong>Effect</strong></th>
<th><strong>Species</strong></th>
<th><strong>NOAEL</strong> (mg/kg)</th>
<th><strong>LOAEL</strong> (mg/kg)</th>
<th><strong>Application Route</strong></th>
<th><strong>Exposure time</strong></th>
<th><strong>Target Organs</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>zeranol</td>
<td>negative</td>
<td>Rat</td>
<td>0.175</td>
<td>1.225</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Endocrine system, Liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dog</td>
<td>0.25</td>
<td>1.25</td>
<td>Oral</td>
<td>14 Weeks</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rat</td>
<td>0.1</td>
<td>0.8</td>
<td>Oral</td>
<td>26 Weeks</td>
<td>Male reproductive organs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dog</td>
<td>0.025</td>
<td>2.5</td>
<td>Oral</td>
<td>29 Weeks</td>
<td>Reproductive organs, Bone marrow, Bladder</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>hair loss</td>
</tr>
</tbody>
</table>

### Repeated dose toxicity

#### Components:

<table>
<thead>
<tr>
<th><strong>Component</strong></th>
<th><strong>Effect</strong></th>
<th><strong>Species</strong></th>
<th><strong>NOAEL</strong> (mg/kg)</th>
<th><strong>LOAEL</strong> (mg/kg)</th>
<th><strong>Application Route</strong></th>
<th><strong>Exposure time</strong></th>
<th><strong>Target Organs</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>zeranol</td>
<td>negative</td>
<td>Rat</td>
<td></td>
<td></td>
<td>Oral</td>
<td>13 Weeks</td>
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<td></td>
<td>Oral</td>
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<td>Male reproductive organs</td>
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<tr>
<td></td>
<td></td>
<td>Dog</td>
<td></td>
<td></td>
<td>Oral</td>
<td>29 Weeks</td>
<td>Reproductive organs, Bone marrow, Bladder</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>hair loss</td>
</tr>
</tbody>
</table>
### Species and Effects

**Dog, female**
- **LOAEL**: 15 mg/kg
- **Application Route**: Oral
- **Exposure time**: 7 y
- **Target Organs**: female reproductive organs
- **Symptoms**: Changes in the blood count

**Monkey, female**
- **Application Route**: Oral
- **Exposure time**: 10 y
- **Target Organs**: female reproductive organs

### Boric acid

**Species**: Rat
- **NOAEL**: 100 mg/kg
- **LOAEL**: 334 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 2 y

### Magnesium stearate

**Species**: Rat
- **NOAEL**: > 100 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days
- **Remarks**: Based on data from similar materials

#### Aspiration toxicity
Not classified based on available information.

#### Experience with human exposure

**Components**

| Ingestion | Remarks | May cause adverse reproductive effects. |

### Ecotoxicity

#### Components

**Boric acid**
- **Toxicity to fish**: LC50 (Pimephales promelas (fathead minnow)): 74 mg/l
  - Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Ceriodaphnia dubia (water flea)): 102 mg/l
  - Exposure time: 48 h
- **Toxicity to algae/aquatic plants**: EC50 (Pseudokirchneriella subcapitata (green algae)): 52.4 mg/l
  - Exposure time: 72 h
  - **Method**: OECD Test Guideline 201
### NOEC (Pseudokirchneriella subcapitata (green algae)):
- **Exposure time:** 72 h
- **Method:** OECD Test Guideline 201

### Toxicity to fish (Chronic toxicity):
- **NOEC (Danio rerio (zebra fish)):** 6.4 mg/l
- **Exposure time:** 34 d
- **Method:** OECD Test Guideline 210

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- **NOEC (Daphnia magna (Water flea)):** 10.8 mg/l
- **Exposure time:** 21 d

### Toxicity to microorganisms:
- **EC10:** 35.4 mg/l
- **Exposure time:** 3 h
- **Method:** OECD Test Guideline 209

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### Magnesium stearate:

#### Toxicity to fish
- **LC50 (Leuciscus idus (Golden orfe)):** > 100 mg/l
- **Exposure time:** 48 h
- **Method:** DIN 38412
- **Remarks:** Based on data from similar materials

#### Toxicity to daphnia and other aquatic invertebrates
- **EL50 (Daphnia magna (Water flea)):** > 1 mg/l
- **Exposure time:** 47 h
- **Test substance:** Water Accommodated Fraction
- **Remarks:** Based on data from similar materials
  - No toxicity at the limit of solubility.

#### Toxicity to algae/aquatic plants
- **EL50 (Pseudokirchneriella subcapitata (green algae)):** > 1 mg/l
- **Exposure time:** 72 h
- **Test substance:** Water Accommodated Fraction
- **Method:** OECD Test Guideline 201
- **Remarks:** Based on data from similar materials
  - No toxicity at the limit of solubility.

#### Toxicity to microorganisms
- **NOELR (Pseudokirchneriella subcapitata (green algae)):** > 1 mg/l
- **Exposure time:** 72 h
- **Test substance:** Water Accommodated Fraction
- **Method:** OECD Test Guideline 201
- **Remarks:** Based on data from similar materials

#### Toxicity to algae/aquatic plants
- **EC10 (Pseudomonas putida):** > 100 mg/l
- **Exposure time:** 16 h
- **Test substance:** Water Accommodated Fraction
- **Remarks:** Based on data from similar materials
SAFETY DATA SHEET

Zeranol Formulation

Persistence and degradability

Components:

zeranol:

Biodegradability: Result: Not readily biodegradable.
                 Biodegradation: 50 %
                 Exposure time: 91 d

Magnesium stearate:

Biodegradability: Result: Not biodegradable
                 Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

zeranol:

Partition coefficient: n-octanol/water: log Pow: 3.13

Boric acid:

Bioaccumulation: Species: Cyprinus carpio (Carp)
                 Bioconcentration factor (BCF): <= 3.2
                 Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water: log Pow: -1.09

Magnesium stearate:

Partition coefficient: n-octanol/water: log Pow: > 4

Mobility in soil

Components:

zeranol:

Distribution among environmental compartments: log Koc: 2.95

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues: Dispose of in accordance with local regulations.
                     Do not dispose of waste into sewer.
Contaminated packaging: Empty containers should be taken to an approved waste
                     handling site for recycling or disposal.
                     If not otherwise specified: Dispose of as unused product.
SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Combustible dust
- Carcinogenicity
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

SARA 313
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
zeranol 26538-44-3
D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate 64044-51-5
Magnesium stearate 557-04-0
Boric acid 10043-35-3

California Permissible Exposure Limits for Chemical Contaminants
Magnesium stearate 557-04-0

The ingredients of this product are reported in the following inventories:
SECTION 16. OTHER INFORMATION

Further information

**NFPA 704:**

- Flammability: 0
- Health: 2
- Instability: 0

**HMIS® IV:**

- Health: *3
- Flammability: 2
- Physical Hazard: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The “*” represents a chronic hazard, while the “/” represents the absence of a chronic hazard.

**Full text of other abbreviations**

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- CAL PEL: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
- OSHA Z-3: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
- CAL PEL / PEL: Permissible exposure limit
- OSHA Z-3 / TWA: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organiza-

Revision Date: 04/04/2023

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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